

DETAILED ACTION

1. This Office action is based on the 10/579,877 application filed on March 18, 2006 which is a 371 National Entry of PCT/EP03/12888 filed on November 18, 2003.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

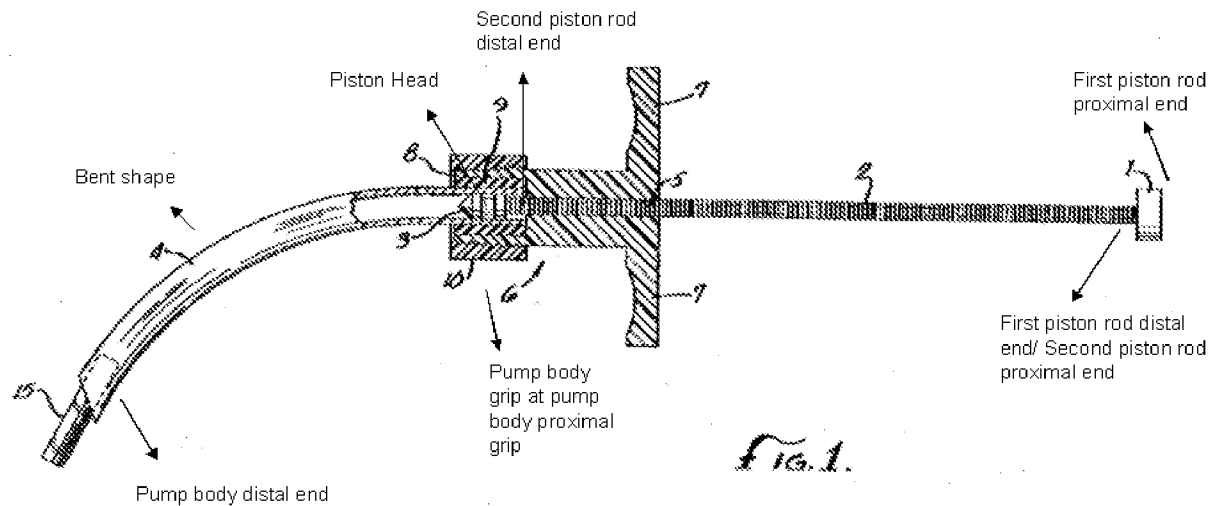
3. **Claims 4-5, 7, 14-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Swaniger US 4,769,011.

Regarding **Claim 15**, Swaniger discloses an injection pump comprising:

a pump body with a distal and proximal end, a length measured between the ends and a pump body grip at the proximal end (see Fig below), the body comprising a flexible material (see Col lines 24-26);

a piston system with a first rigid piston rod and a second piston rod, each with a distal end and proximal end, a piston head at the second rod distal end (see Fig below),

wherein the piston head is moveable along the entire pump body length, the length measured between the proximal end and distal end of the pump body (see Fig below and Col 4 lines 60-68).



Regarding **Claims 4-5, 7**, Swaniger discloses the pump body has a rigid shape bent shape (see fig above) and the flexible rod conforms to the bent shape, wherein the second piston distal end is flexible (see Col 3 lines 45-50).

Regarding **Claim 14**, Swangiger discloses the pump body is arranged at the pump body grip (see Fig above in claim 1) rotatable and replaceable (see fig above in claim 1 and Col 5 lines 20-40, where the pump body can be rotated and removed from the body grip and replaced if one chooses to do so).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Swaniger US 4,769,011 in view of Fischione US 4,655,749.

Swaniger discloses the claimed invention as discussed above but does not disclose sealing rings.

However Fischione discloses a piston head with sealing rings (#56) which are used to create a suction effect (see Fig 3 and Col 3 lines 40-44, 60-68 and Col 4 lines 38-66, where rings are provided to seal the chamber and prevent leakage, creating a suction effect when the piston #36 is moved up and down).

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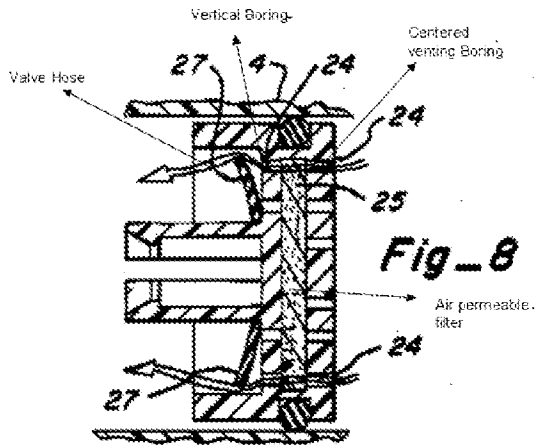
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the injection pump of Swaniger with the sealing rings in view of Fisschione because they prevent leakage of fluid and sealing rings such as O-rings are well known in the art for creating a suction effect within an injection pump device.

8. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Swaniger US 4,769,011 and Fischione US 4,655,749, as applied to claim 8 above, and in further view of Baidwin et al US 5,238,003.

The combination of Swaniger and Fischione disclose the claimed invention as discussed above but does not specifically disclose the end piston head has a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose.

However, Baidwin discloses a similar injection pump with an end piston head with a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose (as seen in Fig below), where it allows for passage of air but is impervious to fluids (See Col 4 lines 6-18).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Swaniger and Fischione to include the filter and venting boring and valve hose in view of Baidwan as taught above because it allows for passage of air but is impervious to fluids.

9. **Claims 4, 5, 7, 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Carfagni US 2,903,794 in view of Leopoldi et al US 4,743,234 and Goodhugh US 833,044.

Carfagni discloses an injection pump comprising:

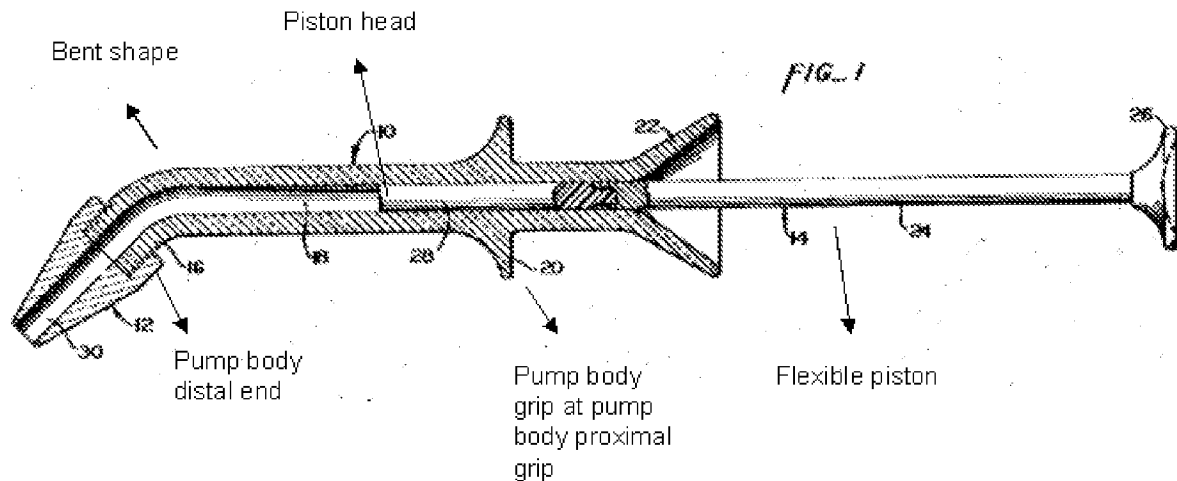
a pump body with a distal and proximal end, a length measured between the ends and a pump body grip at the proximal end (see Fig below),

a piston system, a piston head at the second rod distal end (see Fig below),

wherein the piston head is moveable along the entire pump body length, the length measured between the proximal end and distal end of the pump body (see Fig below and Col 4 lines 60-68). Carfagni also discloses a bent shape, the piston can conform to the bent shape and the rod is flexible at the distal end (see Fig below and

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Col 1 lines 60-70) and where the pump body is arranged at the grip and is rotatable and replaceable if one chooses to do so (see Col 2 lines 1-6 where the a different pump body can be used with the tip #12).



However, Carfagni does not disclose the pump body is flexible and the piston has a rigid portion.

Leopoldi discloses a similar injection device (see fig 1) that teaches it is known to have markings on pump body to know the amount of proper dosage and known to have the body flexible in order to attach attachments securely onto the body such as a magnifier to more accurately read the markings on the pump body (see Col 1 lines 35-45, Col 5 lines 5-10). Goodhugh discloses a similar injection device with a bent shape (see fig 1) with a first rigid piston rod (#4) with distal and proximal ends, the distal end attached to a second flexible piston rod (#5) also having proximal and distal ends, the distal end having a piston head, wherein the piston allows for only the distal flexible end to conform to the bend (see lines 35-40).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pump body of Carfagni to include markings and be flexible in view of Leopoldi because the markings allow one to see the proper of dosage to be injected and the flexibility of the body allows for firm connectivity of attachments such as a magnifier to better read the markings. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Caragni and Leopoldi to include a first rigid piston rod in view of Goodhugh because it applies a known technique to a known device ready for improvement to yield predictable results of providing a piston rod to a bent shaped body, wherein the distal end of the piston rod can conform to the bend.

10. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Carfagni US 2,903,794, Leopoldi et al US 4,743,234 and Goodhugh US 833,044, as applied to claim 1 above and in further view of Fischione US 4,655,749.

The combination of Carfagni, Leopoldi and Goodhugh disclose the claimed invention as discussed above but does not disclose sealing rings.

However Fischione discloses a piston head with sealing rings (#56) which are used to create a suction effect (see Fig 3 and Col 3 lines 40-44, 60-68 and Col 4 lines 38-66, where rings are provided to seal the chamber and prevent leakage, creating a suction effect when the piston #36 is moved up and down).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of combination of Carfagni, Leopoldi and Goodhugh to include the sealing rings in view of Fisschione because they prevent

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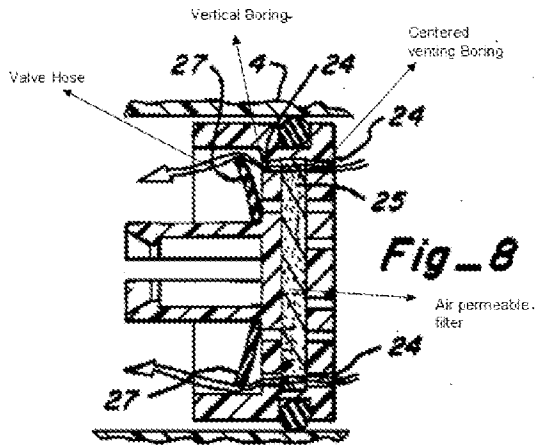
leakage of fluid and sealing rings such as O-rings are well known in the art for creating a suction effect within an injection pump device.

11. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Carfagni US 2,903,794, Leopoldi et al US 4,743,234, Goodhugh US 833,044, and Fischione US 4,655,749, as applied to claim 8 above, and in further view of Baldwin et al US 5,238,003.

The combination of Carfagni, Leopoldi, Goodhugh, and Fischione disclose the claimed invention as discussed above but does not specifically disclose the end piston head has a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose.

However, Baldwin discloses a similar injection pump with an end piston head with a centered venting boring with a rear section equipped with an air-permeable filter, wherein the centered venting boring has a vertical boring which is radially covered with a valve hose (as seen in Fig below), where it allows for passage of air but is impervious to fluids (See Col 4 lines 6-18).

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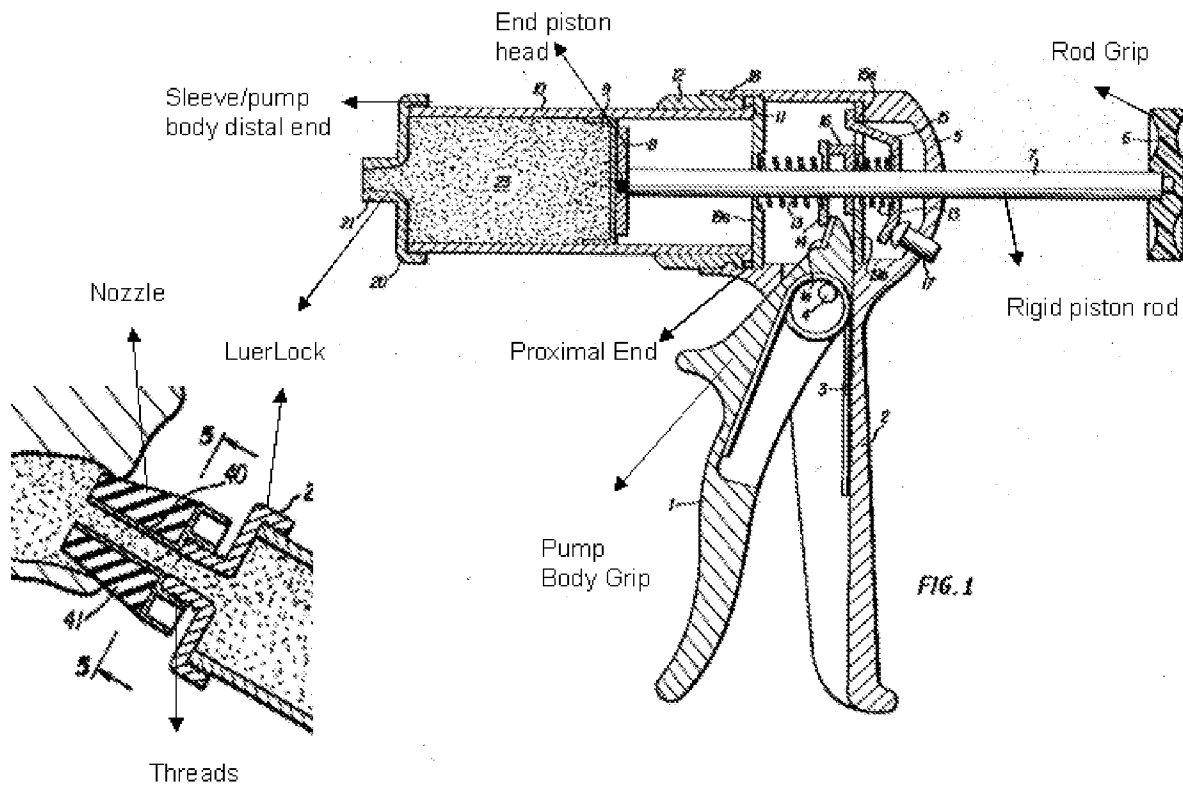
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination of Carfagni, Leopoldi, Goodhugh, and Fischione to include the filter and venting boring and valve hose in view of Baidwan as taught above because it allows for passage of air but is impervious to fluids.

12. **Claims 10, 13, 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller US 4,338,925 in view of Leopoldi et al US 4,743,234 and Scchweizer US 6,086,569.

Miller discloses an injection pump with a pump body with a distal and proximal end, a pump body grip and a piston system. The piston system having a rigid first piston rod with a first piston rod proximal end and distal end with a piston head, the piston head movable between a length from the distal and proximal end. Miller also discloses a hose bracket sleeve with an attached male LuerLock at the distal end and a nozzle screwed to the LuerLock, wherein the male LuerLock is fitted with a prong/thread to fasten the to the pump body by pressure forcing the pump body into place (see fig below and see Col 5 lines 15-26, 30-45 where at the pump body distal end, there is a

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sleeve with threads is attached to a male LuerLock that connects to a nozzle, wherein the threads of the LuerLock extend outward like a prong that engages with the sleeve of the prong body).

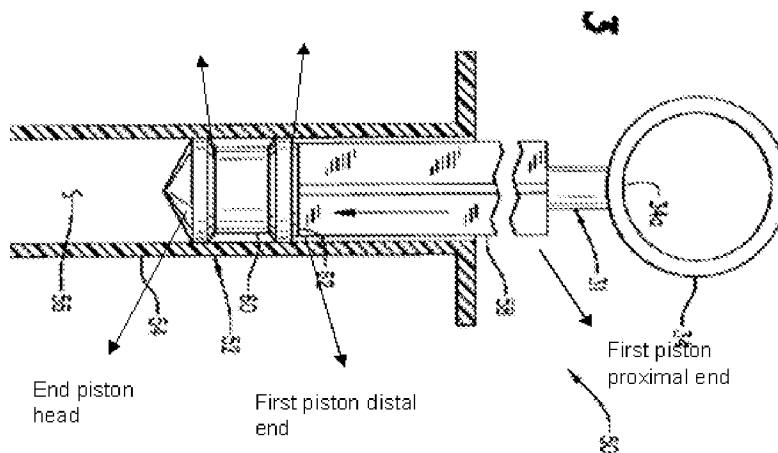


However, Miller does not disclose the piston having a flexible second piston rod with a distal and proximal end and wherein the pump body is made out of flexible material.

Leopoldi discloses a similar injection device (see fig 1) that teaches it is known to have markings on pump body to know the amount of proper dosage and known to have the body flexible in order to attach attachments securely onto the body such as a magnifier to more accurately read the markings on the pump body (see Col 1 lines 35-45, Col 5 lines 5-10). However Schweizer discloses a similar piston system with a rigid

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first piston rod with a distal and proximal end and a flexible second piston rod with a proximal and distal end, wherein the distal end is connected to an end piston head, wherein this configuration allows the end distal head to sealably engage the inner surface of the plunger body to express fluid out of the plunger body (see fig below and Col4 lines 55-65).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pump body of Miller to include markings and be flexible in view of Leopoldi because the markings allow one to see the proper of dosage to be injected and the flexibility of the body allows for firm connectivity of attachments such as a magnifier to better read the markings. It would have also been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Miller and Leopoldi to include a flexible piston rod in view of Schweizer because it applies a known technique to a known device ready for improvement to yield predictable results of providing a piston rod, wherein this configuration allows the end

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distal head to sealably engage the inner surface of the plunger body to express fluid out of the plunger body

13. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Holtz US 1,469,004 in view of Leopoldi US 4,743,234.

Holtz discloses an injection pump for application of highly viscous media that have to be applied with pressure during percutaneous vertebroplasty comprising:

(a) a pump body comprising a pump body proximal end, a pump body distal end, and a pump body length (see Fig below);

(b) a pump body grip fastened at said pump body proximal end (see Fig below);

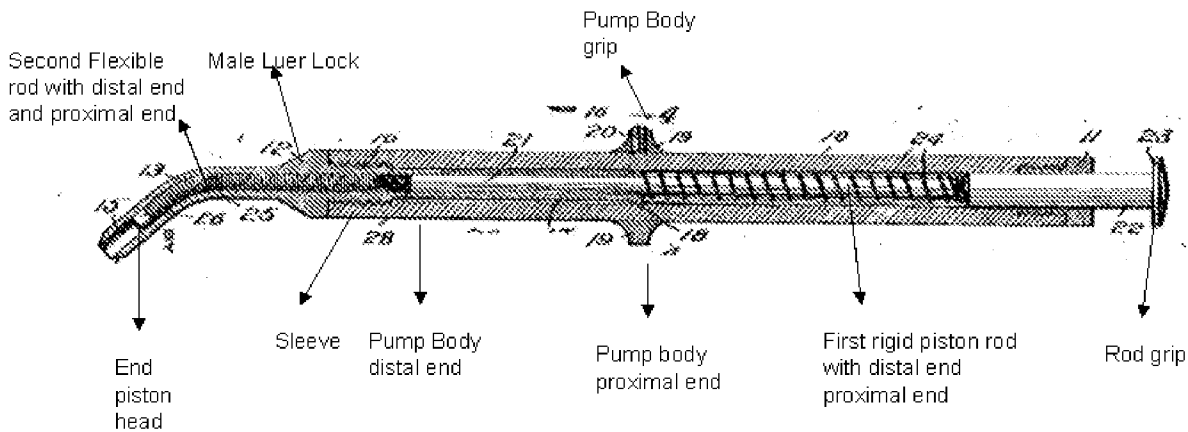
(c) a piston system comprising a rigid first piston rod having a first piston rod proximal end and a first piston rod distal end, a flexible second piston rod connected to said first piston rod at said first piston rod distal end and having a second piston rod distal end, a first piston rod grip connected to said first piston rod at said first piston rod proximal end, and an end piston head at the second piston rod distal end for taking up bone cement (see Fig below and lines 90-100, 24-30); and

(d) a hose bracket sleeve with an attached rotatable male LuerLock at the pump body distal end (see fig below and lines 65-70, where a sleeve surrounds the LuerLock, where the LuerLock is a male component threaded onto the sleeve);

wherein said end piston head is movable along the pump body length from the pump body proximal end to the attached LuerLock at the pump body distal end (see Fig

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below).



However, Holtz does not specifically disclose the pump body is flexible.

Leopoldi discloses a similar injection device (see fig 1) that teaches it is known to have markings on pump body to know the amount of proper dosage and known to have the body flexible in order to attach attachments securely onto the body such as a magnifier to more accurately read the markings on the pump body (see Col 1 lines 35-45, Col 5 lines 5-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pump body of Holtz to include markings and be flexible in view of Leopoldi because the markings allow one to see the proper of dosage to be injected and the flexibility of the body allows for firm connectivity of attachments such as a magnifier to better read the markings.

Response to Arguments

14. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection. The examiner contacted the applicant to try and perform an examiner's amendment to get the case in condition for allowance. See interview summary attached.

Conclusion

15. Applicant's amendment (in claims 15-16) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone

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number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733